LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK



Examples

- Accessories •
- Wash buffers •
- Specimen receptacles
 - Instruments •
 - Culture media •







HIGH PERSONAL RISK, MODERATE TO LOW PUBLIC **HEALTH RISK**

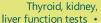
Examples



- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers (screening and diagnosis)
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
- Cardiac markers
- Tissue typing e.g. HLA

MODERATE TO LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK





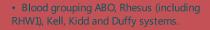
- Infertility assays •
- Clinical chemistry •
- Hormones, enzymes, proteins Inf ammatory markers
 - Rheumatology markers •
 - Self-test devices that are not Class C: pregnancy, fertility, cholesterol and urine tests for glucose, erythrocytes, leucocytes and bacteria



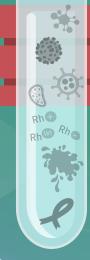


HIGH PUBLIC HEALTH RISK, HIGH PERSONAL RISK

• Blood donation screening e.g. Syphilis,



• Diagnostic test e.g. HIV 1/2



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